

REMARKS/ARGUMENTS

Claims 1-23 and 38-59 are pending. Claims 9, 12, 19, 21, 23, 44, and 46 were previously withdrawn. Claims 1-8, 10, 11, 13-18, 20, 22, 38-43, 45, and 47-59 are under examination and stand substantively rejected. Reconsideration is respectfully requested.

Overview of Rejection (based on Rearrangement of Parts)

The gist of the rejection is at page 10 of the Office Action, which states that rearranging parts of an invention involves only routine skill. It is noted, however, that there are important exceptions to this general rule. For example, MPEP 2144.04 (VI)(C) [*"Rearrangement of Parts"*] provides the following caveats:

- (1) the proposed modification must not modify the device functionality; and
- (2) the cited reference must provide motivation for the artisan, without the benefit of Applicant's specification, to change the reference device.

At page 4, lines 4-11 of the Office Action, it is alleged that switching the location of Hooven's sensor (168) with the pacing/sensor pair (172/174) provides the same intended functionality.

Applicants provide herewith evidence in the form of a Rule 1.132 Declaration by Dr. David K. Swanson [*"the Swanson Declaration"*]. The Declaration provides objective evidence from a knowledgeable and respected source.

As noted in the Swanson Declaration, and as further discussed below, relocating Hooven's pacing/sensor pair (172/174) and sensors (168) modifies the intended function stated by Hooven. Moreover, the proposed modification would not have been obvious to the artisan at the time of invention. Hence, the Swanson Declaration provides objective evidence of patentability, and thus rebuts the alleged *prima facie* case of obviousness.

Relocating Hooven's Pacing/Sensing Pair (172/174) Modifies Function

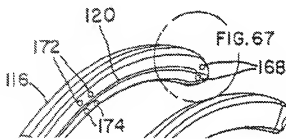


Fig. 66 of Hooven

Hooven gives a specific functional reason as to why the pacing/sensor pair 172/174 is located on opposing sides of electrode 120. For example, at col. 15, lines 27-47, Hooven explains that pacing/sensing continues as electrode 120 creates the lesion, and when the lesion is formed, sensor 174 no longer detects pacing 172 signal.

Hence, the intended functionality of pacing/sensing electrodes 172/174 depends upon the lesion being formed *between* the pacing electrode 172 and the sensing electrode 174. If Hooven's pacing/sensing electrodes 172/174 were moved distal to electrode 120, the pair would no longer operate as intended, because they would no longer be located on opposing sides of a lesion that is formed by electrode 120, and would not be used to determine when the lesion is complete as described by Hooven.

Put differently, if pacing/sensing electrodes 172/174 were placed distal to electrode 120, to the location of sensor 168, then it would be possible to linearly traverse the distance between pacing electrode 172 and sensing electrode 174 *without* intersecting electrode 120. However, the stated functionality of Hooven requires that a linear traverse from pacing electrode 172 to sensing electrode 174 must intersect electrode 120.

Based on the above, and sections 11 and 12 of the Swanson Declaration, relocation of Hooven's pacing/sensing Pair (172/174) modifies the device functionality, which is contrary to guidance provided in MPEP 2144.04 (VI)(C).

Relocating Hooven's Sensors (168) Modifies Function

Hooven also provides a specific functional rationale as to why sensors 168 are located at the distal tip of the jaw member. For example, at col. 15 line 54 to col. 16 line 6, Hooven explains that it is important to monitor the EKG of the distal tip of the grasper, so that damage to the mitral valve annulus can be avoided. The surgeon uses the distal sensors 168 in order to:

“facilitate accurate *placement of the jaw tip* on the mitral valve annulus, and away from the mitral valve leaflets.” (Emphasis added)

Hence, the intended functionality of sensors 168 depends upon those sensors being located at the distal tip of the jaw. If Hooven's sensors 168 were moved away from the tip to a central location (e.g. to the position of pacing/sensor pair 172/174 on Fig. 66), then sensors 168 would no longer operate as intended, because they would no longer be used to accurately facilitate placement of the jaw tip as described by Hooven.

Based on the above, and sections 13-15 of the Swanson Declaration, relocation of Hooven's sensors (168) modifies the device functionality, which is contrary to guidance provided in MPEP 2144.04 (VI)(C).

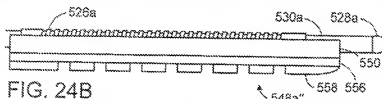
Proposed Modification Destroys Hooven's Intended Functionality

According to MPEP 2143.01 (V), if proposed modification would render the cited reference unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. Applicants submit that the proposed modification requires an unusual and unforeseeable reconfiguration of Hooven that would render Hooven's device unsatisfactory for its intended purpose of (a) locating a pacing/sensing pair 172/174 on opposing sides of an ablation electrode so as to detect a lesion formed therebetween, and (b) locating sensors 168 at the distal tip so as to accurately place the jaw tip on the mitral valve annulus.

In sum, in order for Hooven to function as intended, pacing/sensing electrode pair 172/174 **must remain** on opposing sides of electrode 120, and sensors 168 **must remain** at the distal tip of the jaw.

Presently Claimed Stimulation Element Location Is Beneficial

Presently pending independent claim 1 involves an apparatus wherein a distal end of the stimulation element is disposed distal to a distal end of the coagulation element. Aspects of this feature are shown in the embodiment of Fig. 24B (reproduced below).



Specifically, this drawing shows a distal end of stimulation electrode 528a disposed distal to a distal end of coagulation electrode 526a. As explained in the instant application at, for example, page 27, lines 31-33, such arrangements allow a physician to test various locations during lesion formation, without moving the probe.

During a treatment, tissue adjacent to the ablation electrode becomes heated. However, because overheated tissue does not respond to pacing, a pacing electrode that is located directly at the ablation electrode may be ineffective in stimulating the adjacent tissue.

In contrast, a stimulation electrode that located away from the coagulation electrode can effectively stimulate the adjacent tissue, because that tissue is not overheated. For similar reasons, the presently claimed stimulation element, which is distal to a distal end of the coagulation electrode, allows the physician to test various locations during lesion formation because the stimulation element can stimulate tissue that is not overheated.

For at least the reasons above, and sections 17-21 of the Swanson Declaration, it is submitted that the location of the stimulation electrode provides a particular functionality to the presently claimed apparatus, and that such configurations do not represent a mere rearrangement of parts.

First Rejection Under 35 U.S.C. §103

Claims 1-8, 13-18, 22, 38-43, 45, 47-49, and 52 were rejected under 35 U.S.C.

§103(a) as allegedly obvious over US 6,807,968 ["Francischelli"] in view of US 6,277,117 ["Tetzlaff"] and US 6,889,694 ["Hooven"]. This rejection is traversed.

It is well established that a *prima facie* case of obviousness requires, among other things, a showing that all claim elements are considered when determining patentability against the cited references. Applicants submit that the combination of Francischelli, Tetzlaff, and Hooven does not meet this test as applied to the presently pending claims.

Independent Claim 1

Presently pending claim 1 is drawn to an apparatus for use with a clamp. The apparatus includes, among other things, a base member with a mating structure and a groove, a support member, a coagulation element, and a stimulation element. The stimulation element is disposed distal to a distal end of the coagulation element.

The pacing electrode 172 of Hooven cannot read on the presently claimed stimulation element. As shown at Figs. 66 and 67 of Hooven, a distal end of the pacing electrode 172 is not disposed distal to a distal end of the RF ablation electrode 120. Nor is there a teaching or suggestion that the distal end of pacing electrode 172 would be disposed distal to a distal end of the conductive coil 30A of Francischelli or the electrode 110 of Tetzlaff.

Because the combination of Francischelli, Tetzlaff, and Hooven does not result in an apparatus where a distal end of a stimulation element is disposed distal to a distal end of the coagulation element, the combination does not support a *prima facie* case of obviousness.

Independent Claim 14

Presently pending claim 14 is drawn to an apparatus having a clamp, a base member, a support member, a coagulation element, and a stimulation element. A distal end of the stimulation element is disposed distal to a distal end of the support member.

For at least the reasons provided above with regard to claim 1, Applicants submit that the combination of Francischelli, Tetzlaff, and Hooven does not result in an apparatus where

a distal end of the stimulation element is disposed distal to a distal end of the support member, and thus the combination does not support a *prima facie* case of obviousness.

Independent Claim 38

Presently pending claim 38 is drawn to a system having support member and a stimulation element, where a distal end of the stimulation element is disposed distal to a distal end of a base member.

For reasons similar to those provided above with regard to claim 1, Applicants submit that the combination of Francischelli, Tetzlaff, and Hooven does not result in a system where a distal end of a stimulation element is disposed distal to a distal end of a base member, and thus the combination does not support a *prima facie* case of obviousness.

Independent Claim 47

Presently pending claim 47 is drawn to apparatus having a base member, a support member, a coagulation means, and a stimulation means. The distal end of the means for transmitting stimulation energy is disposed distal to a distal end of the means for transmitting coagulation energy, distal to a distal end of the support member, and distal to a distal end of the base member.

For reasons similar to those provided above with regard to claim 1, Applicants submit that the combination of Francischelli, Tetzlaff, and Hooven does not result in a system where a distal end of the means for transmitting stimulation energy is disposed distal to a distal end of the means for transmitting coagulation energy, distal to a distal end of the support member, and distal to a distal end of the base member, and thus the combination does not support a *prima facie* case of obviousness.

With regard to the presently pending dependent claims, claims 2-8 and 13 depend from claim 1, claims 15-18 depend from claim 14, claims 39-43 and 45 depend from claim 38, and claims 48-49 and 52 depend from claim 47. These dependent claims are therefore allowable as depending from allowable base claims, as well as for the nonobvious combination of elements they recite. Withdrawal of this rejection is requested.

Second Rejection Under 35 U.S.C. §103

Claims 10, 20, and 50 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Francischelli in view of Tetzlaff, Hooven, and known subject matter. Applicants request reconsideration of claims 10, 20, and 50 in view of the independent claims from which they depend.

Third Rejection Under 35 U.S.C. §103

Claims 11 and 51 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Francischelli in view of Tetzlaff, Hooven, and known subject matter. Applicants request reconsideration of claims 11 and 51 in view of the independent claims from which they depend.

Fourth Rejection Under 35 U.S.C. §103

Claim 55 was rejected under 35 U.S.C. §103(a) as allegedly obvious over Francischelli in view of Tetzlaff, Hooven, and US 6,032,674 ["Eggers"]. Applicants request reconsideration of claim 55 in view of the independent claim from which it depends.

Fifth Rejection Under 35 U.S.C. §103

Claim 56 was rejected under 35 U.S.C. §103(a) as allegedly obvious over Francischelli in view of Tetzlaff, Hooven, and US 6,558,408 ["Fogarty"]. Applicants request reconsideration of claim 56 in view of the independent claim from which it depends.

Respectfully submitted,

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Attachments: Rule 1.132 Declaration by Dr. David K. Swanson (including CV)

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